Coronary Atherectomy: Report of the First Experience in Hawaii

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Since Andreas Gruentzig[1] first introduced percutaneous transluminal coronary angioplasty (PTCA) in 1977, the ability to revascularize occluded coronary vessels with a catheter has enjoyed an explosive and unimaginable growth. As the equipment and operator experience improved, the possibilities appeared boundless. However, balloon angioplasty is hampered by a significant restenosis rate in the dilated vessel (approximately 30%), which is higher in selected locations (up to 60% in the proximal left anterior descending artery), even in the best of hands. This fundamental limitation may in part be due to the actual nature of the technique itself—stretching the vessel and fissuring the plaque causing remodeling without removal. The uneven, exposed vessel surface post-plaque rupture may contribute to activation of the hemostatic system, with acute thrombosis and release of various platelet and endothelial-derived growth factors, leading to long-term tissue proliferation and restenosis. Atherectomy, the mechanical removal of plaque from the vessel wall, appears to be an answer. This process actually debulks the culprit tissue and leaves behind a smoother, presumably less thrombogenic surface. We wish to report our first experience with a specific form of this technique in 4 consecutive patients, with a brief discussion of its promises and limitations.

Technique

Atherectomy currently can be performed percutaneously by a catheter. There are 3 major techniques: Directional, rotational and extractional. Only the directional form is approved by the FDA for coronary circulation and was the technique used in all our patients.

Directional atherectomy was developed by John B. Simpson MD at Sequoia Hospital in Redwood City, California in 1985, first for the peripheral vessels of the human body. Coronary work started in 1986[2]. The directional coronary atherectomy (DCA) catheter basically consists of a cup-shaped cutter housed in a rigid cylindrical metallic case at the catheter tip. This case has a longitudinal window along one side and an inflatable long balloon on the opposite side. There is a flexible nose cone which serves to hold back the cut tissue and also minimizes tissue trauma as the catheter is advanced inside the vessel. The entire catheter is guided by a steerable 0.014 inch guide-wire which is threaded coaxially through the entire catheter (including the cutter). The cutter is connected by a hollow cable to a hand-held, battery-driven motor unit that spins the cutter at 2,000 rpm. The cutter can be manually advanced or retrieved by a proximal lever.

During the procedure, the catheter is delivered to the culprit vessel in a 10 or 11 French guiding catheter, introduced percutaneously through the femoral artery. The technique is similar to PTCA. The lesion is traversed with the guide-wire, over which the catheter is advanced. The opening in the distal casing is then oriented across the lesion. The balloon is inflated by a manually controlled device with pressures of 10 to 40 psi, to push the window against the atheromatous plaque. The cutter is withdrawn, the drive unit is turned on, and the spinning cutter is slowly advanced across the window, shearing off the tissue in the process (Figure 1). The balloon is deflated and the catheter is torqued manually 45° to 90° to orient the window to a different part of the plaque. The process is then repeated. The cuts are generally made circumferentially (360°) or directionally if the plaque is eccentric, with progressively increasing balloon inflation pressures, to allow for deeper cuts. A larger device can be used if the end result is less than satisfactory (the AtheroCath is available in 3 sizes: 5F, 6F and 7F).

Simpson had previously recommended leaving a residual lesion of no more than 30%. The current practice is to make the vessel as normal appearing as possible as there is increasing evidence to suggest that a more complete atherectomy reduces restenosis[3].

The patients are all premedicated with aspirin and fully anticoagulated with intravenous heparin at the time of the procedure, maintaining an activated clotting time of >350 sec. Post-procedure, because of the size of the arterial sheath, close attention must be paid to the circulatory status of the distal extremity. It is common practice to remove the sheath on the same day.

The concept is highly attractive, ie the mechanical removal of the offending plaque. In reality, much of the angiographic improvement following DCA is due to the Dotter effect, much akin to the mechanism of PTCA action—a physical dilatation of the lumen with the catheter and the inflated balloon[4]. Therefore, it behooves the operator to avoid using excessively high inflation pressures, such that there is more cutting and less dottering. It is estimated that actual tissue removal contributes to about 25% of the angiographic luminal improvement[5].

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Close at hand

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Case reports

Case No. 1 is a 70-year-old housewife with hypertension, hypercholesterolemia, type II diabetes mellitus and idiopathic hypertrophic subaortic stenosis (IHSS). She had exertional angina and was found to have serial (75%, 90%) proximal left anterior descending (LAD) and 80% proximal ramus intermedius lesions, with vigorous left ventricular (LV) systolic function and ejection fraction (EF) over 75%. She had undergone successful PTCA of the above lesions. Three months later, she had recurrent angina and was found to have restenosis of a proximal LAD lesion to 90%.

She underwent DCA of her obstruction with a 6 French DVI (Devices for Vascular Intervention, Inc., Redwood City, California) Simpson AtheroCath at our facility. The maximum pressure was 25 psi and a total number of 9 cuts were made circumferentially, reducing the lesion initially to 0%, with six pieces of tissue removed. About half an hour later, the patient developed abrupt hypotension (50 to 60 mmHg systolic) without chest discomfort or electrocardiographic ST-T wave changes. She also had recurrent ventricular tachycardia-fibrillation, requiring direct-current cardioversion.

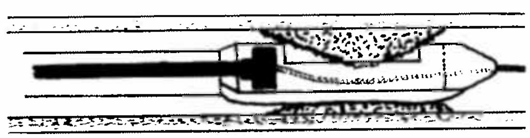
An intra-aortic balloon counterpulsation (IABP) catheter was inserted and 1:1 counterpulsation was begun. Angiography revealed complete occlusion of the LAD beyond the site of atherectomy. The vessel was dilated with a 2.5 mm coronary perfusion catheter. Even though patency was achieved within 15 minutes from the onset of hypotension, the patient remained in shock. She was intubated and ventilated artificially. There was a large output of pinkish fluid from the endotracheal tube, consistent with pulmonary edema. Systolic pressure was only 30mmHg despite maximal pressor and mechanical support.

Figure 1. Mechanism of directional coronary atherectomy (DCA).

A

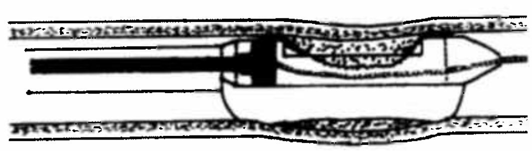
Coronary artery with an eccentric stenosis. A 0.014-inch guide wire has just been threaded across the lesion.

B



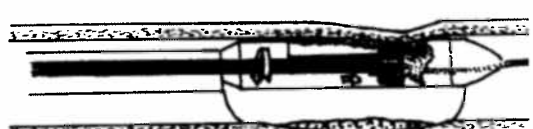
Over the guide-wire, the DVI Simpson AtheroCath is advanced across the obstruction with the window facing the bulk of the eccentric lesion. Note that the wire is coaxial; it runs through the center of the catheter including the cutter (shaded black). The cup-shaped cutter is pulled back proximally before the cut.

C



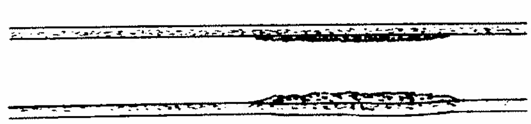
The balloon is inflated to 15 psi pushing the window firmly into the plaque.

D



The drive unit is turned on, spinning the cutter at 2,000 rpm. The cutter then is gently and slowly advanced across the window, shaving off the plaque in the process. The atherectomized tissue is pushed distally into the soft nose cone, which serves as a reservoir.

E



After the cut(s), the catheter and guide-wire are withdrawn.

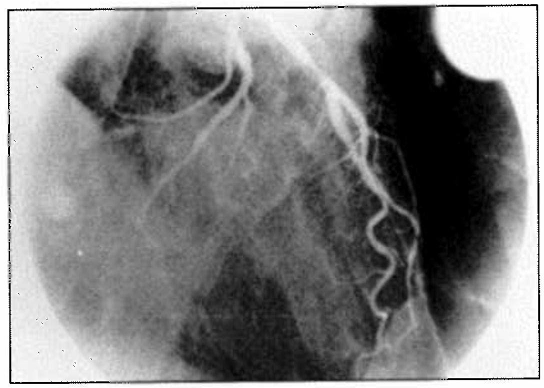


Figure 2A. Case No. 2. Ninety percent proximal left anterior descending (LAD) stenosis.

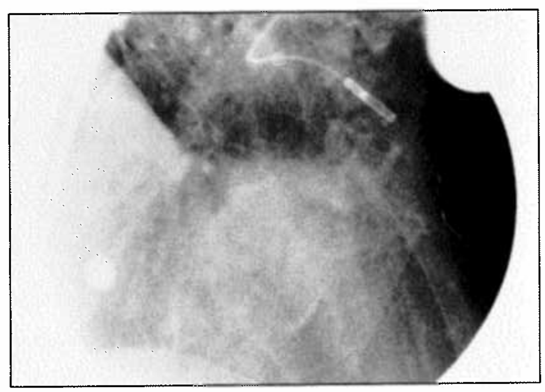


Figure 2B. Seven F AtheroCath across obstruction. The spinning cutter is one-third the way across the cutting window.

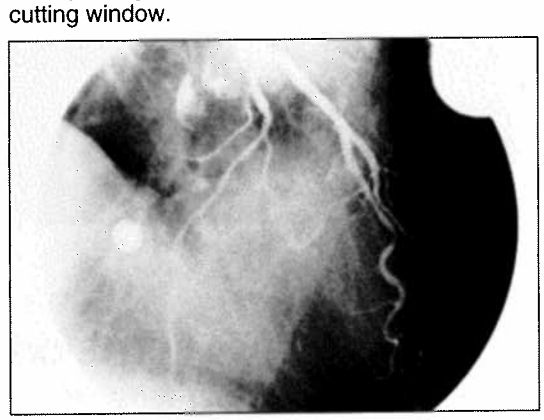


Figure 2C. Same lesion post DCA with residual stenosis of 10%.

The right femoral artery and vein were cannulated and extracorporeal cardiopulmonary bypass with the CPS system was begun. She was moribund when she was brought to the operating room. She received saphenous venous grafting of her LAD and right coronary artery (which had a 50% proximal lesion). The culprit vessel was inspected: there was good antegrade flow without thrombus or perforation.

Somewhat surprisingly, she was easily weaned from cardiopulmonary bypass with the first attempt in the operating room. IABP and pressor support were discontinued by the fourth postoperative day. The maximum creatine kinase (CK) was 4,829 units/L (8.0% MB).

She expired 8 months post-procedure from respiratory failure and urinary sepsis.

Case No. 2 is a 61-year-old retired man with a 45 pack-year smoking history and hypercholesterolemia. He had exertional chest pressure; the treadmill stress test was positive. Catheterization revealed a 90% proximal LAD lesion, 90% proximal circumflex marginal lesion and distal right coronary artery disease. EF was normal at 60%. He had successful PTCA of the LAD and marginal lesions (to 30% and 10% respectively).

Chest pain recurred with restenosis of the LAD lesion to 90% (Figure 2A). Successful DCA was performed, using first a 6F DVI Simpson AtheroCath with a series of 16 circumferential cuts (maximum pressure 35 psi). This was followed by a 7F AtheroCath with 4 cuts (maximum pressure of 20 psi)(Figure 2B). The lesion was reduced to 10% (Figure 2C). Moderate amounts of tissue were removed (Figure 3). CK was normal post procedure. The patient is well after 1 year of follow-up.

Case No. 3 is a 49-year-old man with hypertension and former smoking history. In 1979, because of angina, he had a cardiac catheterization done which revealed LAD disease. In 1989, he had 1-vessel saphenous vein grafting of the LAD done elsewhere. In early 1991, he nearly drowned while bodysurfing. After struggling back to shore, he developed severe, relentless chest pain. He was admitted to our facility with a non-Q wave myocardial infarction. CK was 794 units/L (11.3% MB).

A thallium treadmill test was positive for an anterolateral ischemic defect. Catheterization revealed an 80% mid-lesion in the LAD venous graft, with total occlusion of the LAD proximally (Figure 4A). There was moderate anterior hypokinesis, with EF of 60%. He underwent successful DCA of the graft lesion, with a 7F AtheroCath, employing 16 circumferential cuts (maximum pressure 35 psi) (Figure 4B). The lesion was reduced to 10% (Figure 4C). CK was normal post-procedure. The patient remains pain-free on 10-month follow-up.

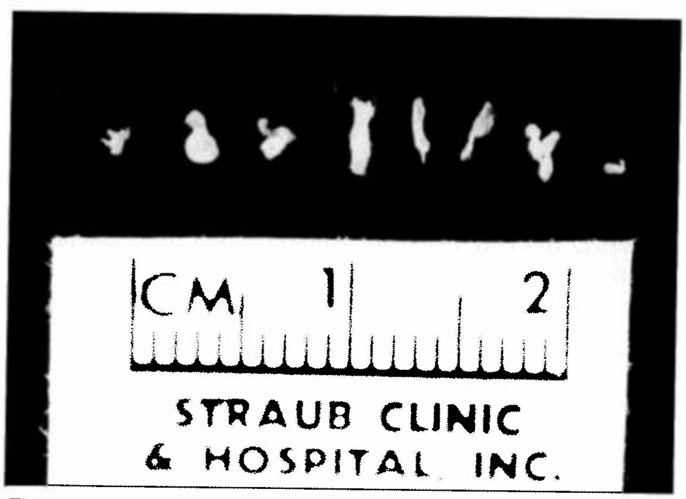


Figure 3. Atheromatous tissue removed from the proximal LAD in patient Case No. 2.

Case No. 4 is a 68-year-old retired man with hypertension. He had onset of severe chest pain in late 1991, with acute anterior MI. Catheterization revealed a 90% proximal LAD lesion involving a diagonal branch which had a 90% ostial occlusion as well. Both occlusions were dilated to 20% by PTCA. With recurrent angina,

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Figure 4A. Case No. 3. Eighty percent mid-lesion in saphenous vein graft to LAD.

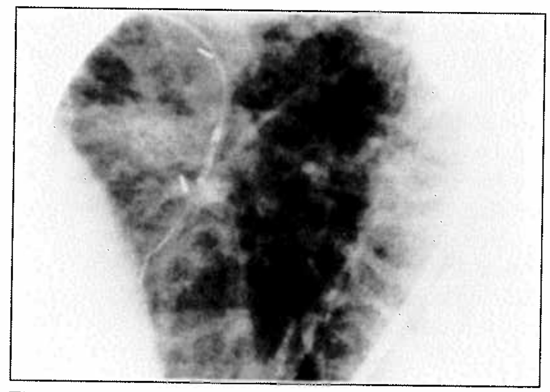
Figure 4B. Seven F AtheroCath across obstruction in graft, with cutter pulled back proximally.

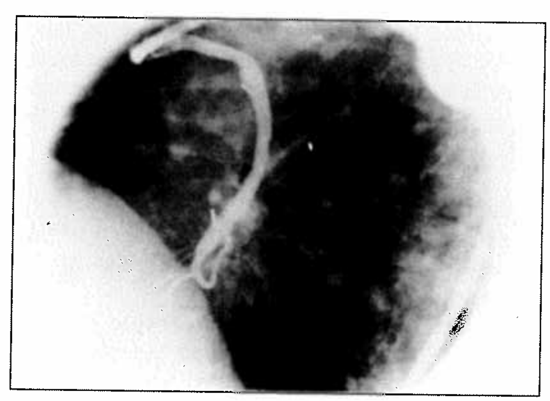
Figure 4C. Same lesion post DCA with residual stenosis of 10%.

he was found to have restenosis of his LAD lesion to 80% eccentrically and the diagonal obstruction to 90% (Figure 5A).

The LAD lesion responded to a successful DCA with a 6F AtheroCath (11 cuts with maximum pressure 20 psi). Moderate amounts of tissue were removed. The lesion was reduced to less than 20%. An attempt was made to make this perfect with a 7F AtheroCath, with 5 cuts at low pressure (10 psi). Unfortunately, this did not remove more tissue but left the vessel with a small nose cone-induced dissection distal to the site of atherectomy (Figure 5B), which was stable and acceptable in appearance (by repeat catheterization next morning). The ostial diagonal obstruction had successful balloon dilation to 20%.

CK was negative afterward. The patient is well after 8-month follow-up.

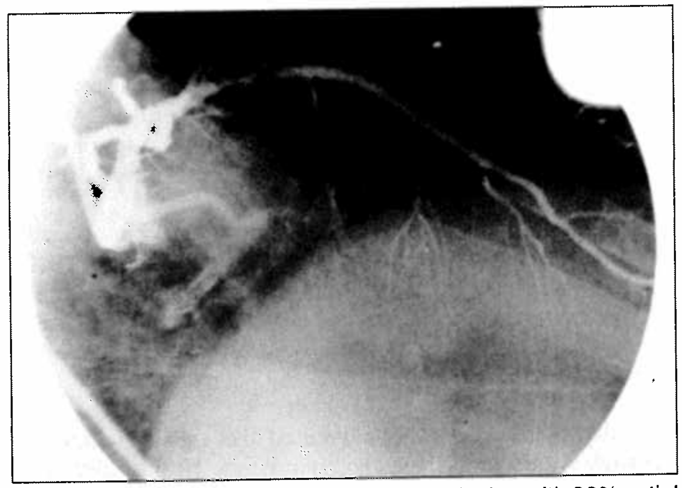

Figure 5A. Case No. 4. 80% eccentric LAD lesion with 90% ostial diagonal stenosis.

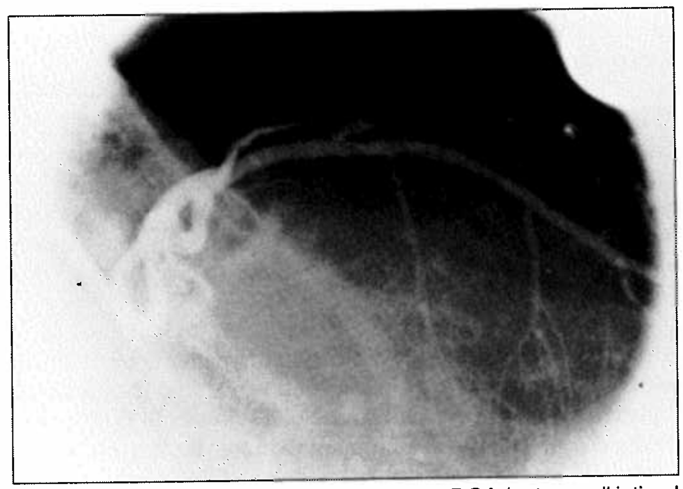

Figure 5B. Residual LAD lesion of 20% post-DCA (note small intimal dissection) and residual diagonal stenosis of 20% post- PTCA.

Discussion

Our results

Our cases are fairly typical of the routine patients considered for DCA. Retrospectively, the choice of Case No. 1 is suboptimal because of underlying IHSS. We now believe that IHSS constitutes a major risk factor for catheter interventional techniques for the LAD, the rationale of which we have reported elsewhere[6]. In our case, the vessel underwent abrupt closure, probably from dissection and/or spasm. Even though patency was reestablished within 15 minutes after acute occlusion, the marked stunning of the massively hypertrophied septum had led to shock, worsening ventricular compliance and outflow obstruction, further decrease in coronary perfusion and spiraling hemodynamic consequences. We could not employ nitrates or calcium entry blockers because the patient was profoundly hypotensive. Immediate establishment of extracorporeal bypass percutaneously allowed us to perfuse the brain and vital organs. The ensuing hypothermia and cardiac decompression during emergent bypass presumably helped reduce myocardial oxygen demand and relax the stiff septum leading to hemodynamic recovery.

The other cases were relatively simple. The technique left a very satisfactory angiographic result (smooth lumen, little to no residual stenosis).

The equipment is rather cumbersome. The guiding catheters from DVI were difficult to maneuver, the 10F being superior to the 11F. The AtheroCath device is a throwback to the early days of PTCA. The trackability is quite poor, and lesions beyond an acute bend are virtually inaccessible. We also are concerned about the ever-present risk of dissecting the vessel with the stiff distal casing, as seen in Case No. 4. For native coronary artery stenosis, it has been our practice to restrict the use of DCA to restenosis after previous PTCA or for very eccentric primary lesions. In bypass grafts, we consider it as a first line catheter interventional technique, in part because the graft size frequently exceeds that of the largest PTCA balloon.

Primary success rate of DCA

Since this is a rapidly growing field, much of the data is available only in abstract form, and the same groups of patients are reported in various permutations.

The multicenter SHAVE (Steerable Housing for AtheroVascular Excision) study, with an experience of 480 patients, revealed that the technique resulted in a primary success rate close to 90%.[2] Noncalcified lesions were better than calcified. There was a trend favoring LAD (over circumflex) and proximal (over ostial) lesions. The study had a significant selection bias because patients with tortuous vessels, diffuse disease or moderate to dense calcification were excluded. Thus the results are not directly comparable to those undergoing PTCA (which in experienced hands has a primary success rate of 96% to 97%, for all lesions). A steep learning curve was also noted in the SHAVE study.

Subsequently, the Sequoia group (which contributed the largest percentage of patients to the various multicenter studies) reported the results of its 848 procedures[7]. Their success rate had increased over time (37% in 1987 and 90% in 1989 and 1990), attesting to the validity of the learning curve. Factors associated with a lower success rate were: Calcified, angled or *de novo* lesions and the use of too small a device.

The American College of Cardiology/American Heart Association Task Force Report on the Guidelines for PTCA[8], classified coronary lesions into types A, B and C (Table 1) with type A occlusions anticipating the highest yield and lowest risk. Ellis et al[9], in their study of 400 stenoses, recognized that DCA, like PTCA, conformed very closely to these criteria for success and complications. The success rates were: Type A 93%, type BI 88%, type B2 75% (there were too few type C lesions for analysis).

Acute complications

Abrupt closure occurred in 4.2% of cases in the multicenter study[10]. This was higher in primary, eccentric, and right coronary artery lesions. Abrupt closure was inversely related to the number of specimens obtained (ie, the more removed the better) and tended to be lower with saphenous venous grafts (p= 0.08). Two-thirds of patients with abrupt closure suffered an MI.

Coronary perforation occurred in 1.3% of cases, none of whom developed tamponade, though one-third of the patients needed emergent bypass surgery[11]. The presence of media and especially adventitia in the excised specimens was correlated strongly with this outcome.

The in-hospital death rate reported by the Sequoia group was 0.35%[7].

There is some concern about peripheral vascular complications because of the large size of the arterial sheaths and guiding catheters. Thus far, an increased incidence has not been reported in literature.

Lesion morphology was found by Ellis et al[9] to have a significant influence on major ischemic complications (death, myocardial infarction and emergency bypass surgery). The complication rates were: Type A 3%, type BI 6%, type B2 13%, type C too few to analyze. In addition, they discovered that stenosis with angulation, proximal tortuosity, decreased preatherectomy minimum lumen dimension and calcification correlated independently with adverse outcome. Extrapolating these data, it may be fair to estimate a major complication rate of 4% to 5% in experienced hands, with a death rate of approximately 0.5%.

Restenosis

Restenosis is the achilles' heel of PTCA and, therefore, the yardstick by which all new catheter interventional techniques will be measured. At least several mechanisms are involved: The elastic recoil of the vessel wall, the activation of the hemostatic system and the stimulation of smooth muscle proliferation post-injury. Debulking the plaque with DCA may reduce elastic recoil; producing a smoother surface may cause less thrombogenesis and smoother flow and hopefully less activation of platelet-derived growth factors.

The Sequoia group reported that restenosis (defined as >50% stenosis evaluated at 6 months) occurred in 36% of native coronaries (31% in primary and 40% in restenosed lesions) and 62% in saphenous venous grafts.[7]

At first glance, DCA does not appear to offer significant advantage over PTCA in terms of restenosis. To address the question, the major randomized CAVEAT (Coronary Angioplasty Versus Excisional Atherectomy Trial) has been started in August, 1991, with the aim of recruiting 1,000 patients by July, 1992. The final report is expected by the end of 1992. This hopefully will provide the much needed answers. Interestingly, Simpson has noted anecdotally that in one of his patients with repeated atherectomies the successive specimens showed progressively decreased proliferative elements. If this observation can be extended to more patients, the solution to restenosis post DCA may well be: "Keep shaving until it stops coming back".

Table 1. ACC/AHA Task Force assigned characteristics of PTCA Type A, B, C lesions[8], as applied to DCA, with success/risk rates per Ellis et al[9].

A*	B**	C***
discrete readily accessible nonangulated nontotal no side branch no Ca++ no thrombus nonostial concentric smooth contour	10-20mm moderate proximal tortuosity >45°, <90° total (<3months) protectable side branch moderate-heavy Ca++ thrombus ostial eccentric irregular contour	>20mm excessive proximal tortuosity >90° total (>3months) unprotectable side branch degenerated friable vein graft
success 93%	success B1 88% B2 75%	
risk 3%	risk B1 6% B2 13%	

* a type A lesion has to fulfill all of the following criteria.
** a type B lesion has any one of the following criteria. Type B1 has one characteristic, type B2 has 2.
*** a type C lesion has any one of the following criteria.

Advantages over PTCA

For highly eccentric and ulcerated lesions, DCA is unquestionably superior to balloon dilatation in achieving satisfactory angiographic results immediately, offering smoother lumen and less residual stenosis. For elastic lesions, typically in the proximal LAD, this technique also offers a clear edge.

DCA also may be a good salvage tool for localized dissections after balloon angioplasty. These flow-occluding tissue flaps are generally very responsive to atherectomy.

At the same time, directional atherectomy offers a unique opportunity to obtain viable tissue for the study of atherogenesis, and this is being actively pursued both at the microscopic[12] and molecular[13] levels, eg it has been found that smooth-muscle-cell migratory velocity is much higher and human non-muscle myosin heavy chain-B mRNA is present in greater abundance in restenotic than in primary plaque material.

Atherectomy by other means

Mechanical Rotational Atherectomy (MRA) or Percutaneous Transluminal Coronary Rotational Ablation (PTCRA) is done by the Rotablator (Heart Technology, Inc., Bellevue, Washington). This instrument consists of an olive-shaped brass burr coated with fine diamond chips and connected to a flexible drive shaft. The burr can rotate at rates of 140,000 to 190,000 rpm, driven by a compressed air turbine. The lesion is first crossed by a special coaxial 0.009-inch guide-wire. The rotating burr is then pushed across the lesion, pulverizing the plaque into microparticles of less than 5 micron diameter, which embolize distally into the coronary micro-

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vasculature and are cleared by the reticuloendothelial system. Initial results were encouraging[14,15]. The immediate success, complication and restenosis rates are equivalent to PTCA. The device is promising for calcified lesions and diffuse disease as well as in tortuous vessels. However, at least a third of the MRA patients require adjunctive PTCA. Furthermore, about 13% of patients demonstrate significant CK rise (≥200 U/L with MB ≥7.5 ng/ml) up to 24 hours post procedure[16].

The Transluminal Extraction Catheter (TEC) (Interventional Technologies, Inc., San Diego, California), is the least well-known of the 3 atherectomy devices. It consists of a hollow torque tube with a distal cutting cone of 2 stainless steel blades. The lesion is first crossed over by a special stiff 0.014-inch guide-wire. The conical cutter is then rotated at 750 rpm by a battery-operated drive unit. Lactated Ringer's solution is continuously infused through the guiding catheter and the debris is suctioned through the hollow tube into a collecting vacuum bottle. The experience with this device is limited. So far, it does not appear to offer any significant advantage over PTCA[17], except that it seems to work well in thrombus-containing lesions[18] (hence a potential role in acute MI), diffuse disease and ostial disease[19]. A fairly large volume of blood may be aspirated along with the debris. At least two-thirds of patients require adjunctive PTCA following this technique. By comparison, less than 15% of patients undergoing DCA require additional balloon dilatation.

The 3 methods of doing atherectomies, at their current level of development, have not surpassed PTCA in terms of ease of use or general applicability and are likely to serve as supplemental techniques. Within that framework, the 3 actually complement each other. For example, for elastic lesions, DCA and TEC are quite suitable. For diffuse disease or for distal lesions in small vessels, MRA may be better. For lesions containing thrombus or for obstructed degenerative saphenous venous grafts with copious, cheesy atheromatous material, TEC has the advantage. For ulcerated lesions, localized dissections and flaps, DCA should be considered. Of the 3, MRA may be the most user-friendly.

Beyond PTCA and atherectomies

The field of catheter interventional techniques is rapidly advancing. Lasers are gaining a strong foothold. Excimer laser coronary angioplasty (ELCA) already has been approved by the FDA for use in diffuse coronary disease and will likely have a useful role in total occlusions and saphenous venous graft lesions, including those appearing degenerative [20]. Other forms of laser energy sources and naked-beam/heated-balloon catheters are under development. Various forms of intracoronary stents[21] also are being studied for treatment of acute dissections/abrupt closure and for the long-term prevention of restenosis.

Ultimately, the solution may be at the molecular level with development of antibodies or factors that will antagonize smooth muscle proliferation and atherogenesis[22] and with the early identification of genomes that are atherosclerosis prone, so that rigid control of risk factors and other preventive measures can be instituted at a young age.

Conclusion

We have presented our early experience in 4 patients who underwent directional coronary atherectomy. It is a helpful adjunctive technique to PTCA; however, there is a steep learning curve and careful patient selection is the key to success. The currently available equipment is quite cumbersome and needs refinement. We have confined its use to recurrent or eccentric native coronary lesions and to primary lesions in clean saphenous-venous bypass grafts. Whether the procedure is more effective than PTCA in reducing restenosis may be answered by an ongoing controlled trial. We look forward to the arrival of other catheter techniques, lasers and stents. It is highly likely that with the additional armamentarium consisting of atherectomy, laser, and stents that most coronary obstructions will be amenable to catheter intervention; emergency coronary bypass for failed PTCA will be a thing of the past. However, we are not looking forward to the proliferation of molecular biologists, who may make interventional cardiologists and cardiovascular surgeons a thing of the past.

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[Hawaii takes pride in its graduate, Scott Bjerke, and in the Armed Forces adjunctive assistance/Ed]

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CORONARY ATHERECTOMY
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ACKNOWLEDGEMENT
The authors thank J Scura and the Straub Cardiac Catheterization Laboratory (J Brennan, K Bridges, L Chun, M Pine, M Warren), E Imoto MD, K Mayeda, R Subia and the Operating Room staff for their tireless support.

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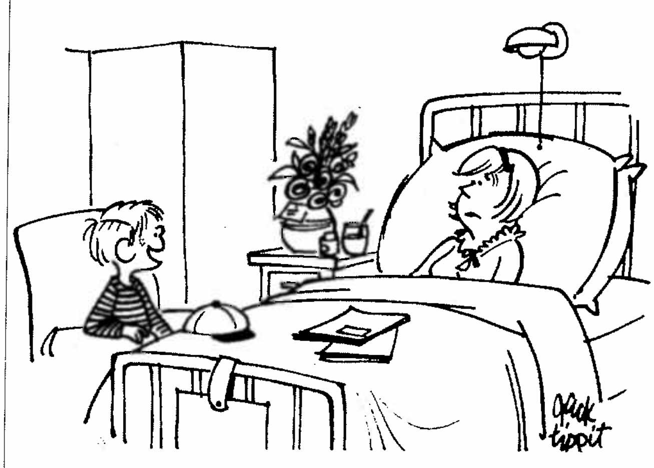

"You don't need to worry 'bout Daddy and me ... we're living in a hotel now that the Health Inspector came and padlocked the house."